

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-51				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number      2			Title of Work Assignment/SF Site Name Meeting Support				
Contractor ICF INCORPORATED, L.L.C.						Specify Section and paragraph of Contract SOW E. Risk Assessment Support - Meetings				
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/10/2015   To   10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling										
Contract Period:                      Cost/Fee:                      LOE: 11/01/2013   To   10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:                      Cost/Fee:                      LOE:										
Cumulative Approved:                      Cost/Fee:                      LOE:										
Work Assignment Manager Name   Thomas O'Farrell  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number   703-347-8085 FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-8523 FAX Number:   703-347-8696			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name   Adam Meier  <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div>							Branch/Mail Code: Phone Number:   513-487-2852 FAX Number:   513-487-2107			

## PERFORMANCE WORK STATEMENT

Contract # EP-C-14-001

WA 2-51

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**TITLE:** Meeting Support for Science and Technology Policy Council and Community of Science Staff and Related Interagency Activities in Support of the EPA Science Advisor

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**Specify Section & Paragraph SOW: E. Risk Assessment Support - Meetings**

**PERIOD OF PERFORMANCE:** CO Approval – October 31, 2016

### **BACKGROUND**

The EPA Science Advisor convenes and chairs the EPA Science and Technology Policy Council (STPC) and Community of Science Staff, which is comprised of senior managers from EPA Offices and Regions. The official STPC representatives are at the Deputy Assistant Administrator and Deputy Regional Administrator level and appropriate level for Offices within the Office of the Administrator. The Science Advisor's priorities for the STPC dovetail with interagency activities, including, but not limited to, the White House Office of Science and Technology Policy (OSTP), National Academies, Government Accountability Office and the Office of Management and Budget. The STPC is supported by a Steering Committee (consisting of Agency Senior Science Advisors) and a small staff within the Office of the Science Advisor (OSA).

The EPA will convene a new Community of Science forum. The Community of Science will convene regular meetings where scientists from across the Agency will meet and discuss science related issues. The Community of Science will be supported by small staff within OSA.

### **TASKS**

Establish Communication Within 3 days after award of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

The Contractor shall also prepare a schedule for deliverables to ensure all materials are properly reviewed, approved, and disseminated.

- 1) The Science Advisor convenes quarterly meetings of the STPC. The Science Advisor may convene additional meetings of the STPC to address specific topics (estimate two special STPC meetings). The EPA Work Assignment (WA) COR will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings in person, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and STPC staff.
- 2) The Community of Science staff convenes up to six meetings of the Community of Science each year.



The EPA WAM will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings by phone, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and Community of Science staff.

- 3) The STPC staff convenes up to 6 meetings of the Peer Review Advisory Group, which reports to the STPC. The EPA WAM will provide meeting logistical information to the contractor in advance. The contractor shall attend the meetings by phone, record the meeting and prepare a concise meeting summary report consisting of action items, decisions, and brief summary of discussions. The contractor shall prepare draft and final meeting summary reports based on comments received from EPA WAM, Technical Representative and STPC staff.
- 4) The STPC and Community of Science staff assist *ad hoc* committees that may be formed at the discretion of the Science Advisor. The contractor shall provide assistance as needed for tasks assigned via Technical Direction from the EPA WAM. Contractor assistance may include: occasional note taking for technical discussions, technical editing of reports, and development of documents, including text, tables, and figures. (Estimate support for 8 *ad hoc* meetings, technical editing of 5 documents, less than 150 pages each).
- 5) STPC activities may require support to develop communication and outreach materials for internal and external stakeholders.

## **DELIVERABLES**

- 1) Draft meeting summary reports within two (2) days.
- 2) Provide EPA WAM with electronic link to the audio recording for STPC meetings within 5 days.
- 3) Provide final documents and reports within five (5) days after receipt of EPA comments on draft reports, meeting summary reports, or other task outputs.

## **CONFLICT OF INTEREST**

The contractor shall disclose any conflict of interest regarding this work.

## **ACCEPTANCE CRITERIA**

Deliverables shall be provided to the EPA WAM in accepted Agency format and be of high quality. Deliverables shall be prepared using software compatible with current ORD computer systems. In some cases, the draft document will be sufficient for the purposes of the STPC staff. Deliverables shall be submitted electronically to the EPA WAM via e-mail as well as hard copy (when requested).

## **MANAGEMENT CONTROLS**

Periodic meetings between the EPA and contractor staff are encouraged to discuss any questions that may arise during performance or completion of this TO. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA TO.

The EPA WAM may identify one or more EPA technical representatives for this TO. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of

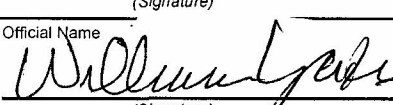
presenting and discussing the information, analyses, results, or presentations related to this TO. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO and the EPAWAM or alternate EPA WAM are the sole representatives of the Contracting Officer authorized to provide technical direction.

**WORK ASSIGNMENT COR (WA-COR):**

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**ALTERNATE WA-COR:**

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Fax: (202) 564-2070

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 2-51	
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:	
Contract Number EP-C-14-001		Contract Period 11/01/2013 To 10/31/2016 Base                      Option Period Number    2	
Contractor ICF INCORPORATED, L.L.C.		Title of Work Assignment/SF Site Name Meeting Support	
Specify Section and paragraph of Contract SOW A.1 and B.1,2,5			
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval		Period of Performance  From 11/10/2015 To 10/31/2016	
Comments:			
<input type="checkbox"/> Superfund		Accounting and Appropriations Data	
		<input checked="" type="checkbox"/> Non-Superfund	
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.			
SFO (Max 2) <input type="checkbox"/>			
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)
	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)
	Amount (Dollars)	(Cents)	Site/Project (Max 8)
	Cost Org/Code (Max 7)		
1			
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Authorized Work Assignment Ceiling			
Contract Period: 11/01/2013 To 10/31/2016		Cost/Fee: \$0.00                      LOE: 0	
This Action:		\$110,104.00                      1,206	
Total:		\$110,104.00                      1,206	
Work Plan / Cost Estimate Approvals			
Contractor WP Dated: 11/30/2015		Cost/Fee: \$110,104.00                      LOE: 1,206	
Cumulative Approved:		Cost/Fee: \$110,104.00                      LOE: 1,206	
Work Assignment Manager Name Thomas O'Farrell		Branch/Mail Code:	
_____ (Signature)                      (Date)		Phone Number 703-347-8085	
		FAX Number:	
Project Officer Name Melissa Revely-Wilson		Branch/Mail Code:	
_____ (Signature)                      (Date)		Phone Number: 919-541-0207	
		FAX Number:	
Other Agency Official Name		Branch/Mail Code:	
_____ (Signature)                      (Date)		Phone Number:	
		FAX Number:	
Contracting Official Name		Branch/Mail Code:	
 12/24/15 (Signature)                      (Date)		Phone Number: 513-487-2852	
		FAX Number: 513-487-2107	

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-53				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016			Title of Work Assignment/SF Site Name				
			Base                      Option Period Number    2			Economic Scenarios and Valuati				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW See Comments					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From 11/12/2015 To 10/31/2016					
Comments: B. Risk Assessment Methods Research and Development D. Analysis, Document and Issue Paper Preparation E. Risk Assessment Support: 1. Science Writing, Risk Communication and Training G. Literature Search										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name Anne Grambsch							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number 703-347-8521			
							FAX Number:			
Project Officer Name Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 703-347-8523			
							FAX Number: 703-347-8696			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name Adam Meier							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 513-487-2852			
							FAX Number: 513-487-2107			

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-53**

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**TITLE: Development of Economic Scenarios and Valuation Information**

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**Specify Section & Paragraph SOW:**

**B. Risk Assessment Methods Research and Development**

**D. Analysis, Document and Issue Paper Preparation**

**E. Risk Assessment Support: 1. Science Writing, Risk Communication and Training**

**G. Literature Search**

**PERIOD of PERFORMANCE: CO approval through 10/31/2015**

**I. PURPOSE**

The purpose of this work assignment is to provide scientific and technical support for the development of economic development scenarios and web-compatible valuation information, to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA). This work assignment is consistent with the purpose and scope of Contract EP-C-14-001 and includes summarizing the relevant literature and preparing background material on the current state of knowledge with respect to economic development projections, updating information on valuation of climate change impacts, updating background white papers on methods and models, and compiling information on existing federal government resources. This effort is intended to provide technical information for use in future assessments of impacts, including National Climate Assessments, and support Agency efforts to adapt to climate change risks.

**II. BACKGROUND**

Future economic development plays a critical role as both a driver of global and environmental change and as a determinant of vulnerability to that change. More specifically, scenarios of future economic development are needed for climate change assessments in general, and health assessments in particular. The US Global Change Research Program (USGCRP) National Assessments led to concerted efforts to develop a range of scenarios and projections in order to better understand the impact of climate change on the US and the national's capability to adapt. While there are well-established methods for developing projections, the USGCRP has not engaged in a sustained effort to develop economic development scenarios that are regional in focus but consistent with global-scale climate scenarios (e.g., SRES Scenarios, RCP scenarios, SSP scenarios). Developing scenarios of changes at fine spatial scales, including economic development, would support multiple agency needs including:

- Assessments of climate change impacts on human health, on water resources, on agriculture and forestry, coastal areas, natural resources, etc. and
- Determining vulnerability of people and infrastructure to climate and weather extremes.

The lack of information about the costs, benefits, and efficiency of actions to respond to climate change risks has been identified as a critical unknown. A key element of support for decision-making is an understanding of the magnitude and distribution across the population of these risks and impacts so that the feasibility, tradeoffs, and equity implications implicit in any decision can be balanced and compared. Several federal agencies have developed models and prepared guidelines for conducting such analyses (e.g., EPA's *Guidelines for Preparing Economic Analysis* (U.S. EPA, 2000), NOAA's *Report of the NOAA Panel on Contingent Valuation* (Arrow et

al., 1993); USACE's *Review of Monetary and Non-Monetary Valuation of Environmental Investments* (Feather et al., 1995)).

Previous work under this Contract (WA 1-53) resulted in:

- Content for a website to be hosted by the USGCRP, including 1) Background text on economic impacts (general framework), economic effect pathways, and measurement techniques for each sector of the National Climate Assessment and 2) Agency economic resource pages;
- Concept and design for a web-based portal 3), and
- A draft report entitled Considerations for Developing Economic Projections for Climate Change Impact, Adaptation, and Vulnerability Analysis.

This Work Assignment is for continuing support during Option Year 2 to:

- Finalize website content based upon feedback from the USGCRP (Task 3);
- Prepare technical sections for the Report, where experts in uncertainty, Integrated Assessment Models, and development of socioeconomic scenarios shall be engaged to prepare and/or review materials developed by ICF (Task 4);
- Attend an experts meeting where near-, medium- and long-term modeling issues and capabilities are discussed and research agenda developed (Task 5);
- Incorporate independent views from experts expressed at the meeting into the Report; and
- Prepare report for posting/publication

### **III. STATEMENT OF WORK**

#### **Task 1: Establish Communication**

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

#### **Task 2: Work Plan and Staffing Plan,**

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of non-market valuation techniques, integrated assessment modeling, economic models, and models for projecting and estimating climate change impacts. The QAPP was prepared under the previous Work Assignment.

#### **Task 3: Finalize Website Content**

Under the previous work assignment, the Contractor updated material on valuation of climate change impacts for NCA sectors and prepared text appropriate for posting as part of a valuation web information portal to be hosted by the USGCRP. The Contractor also inventoried existing documents/resources/websites that have been produced by federal agencies and that include information on costs and values which could be useful to analysts conducting climate change valuation and/or adaptation studies. From these materials, draft Agency write-ups were produced in text appropriate for posting as part of a valuation web information portal to be hosted by the USGCRP. The Contractor shall conduct a final review of internal web links and based upon feedback from the USGCRP, the Contractor shall revise and prepare a final version of website content.

## **Task 4: Prepare Revised Draft Report**

Under a previous work assignment, the Contractor conducted research on the types of models and analyses that are used within EPA and by other Federal Agencies that can be used to project future economic conditions and trends. The Contractor prepared a draft background paper based on public sources that:

- Provides context on the use of economic projections for climate change analyses;
- updates and reviews existing modeling capabilities in the US;
- discusses approaches for producing subnational economics projections; and
- identifies additional considerations in evaluating models and methods, including consistency with SSP scenarios, uncertainty, data issues, complexity and model integration.

The Contractor shall revise the draft report, incorporating input from modeling groups, in-depth materials developed by the Contractor for specific issues that have emerged; and expert reviews of technical material.

### **4.1: Contact Modeling Groups to Review Material and Obtain Information on Specific Modeling Issues**

The Contractor shall contact modeling groups to review material on their models to ensure correctness. In addition, for a small number of the modeling groups (less than 9), the Contractor shall engage in more specific discussions of various issues, possibly including:

- (1) consistency with SSPs (e.g., how flexibility does their model have to build in storylines and/or match national level data);
- (2) for their model, what are the implications of alternative methods for developing subnational projections, including questions of internal consistency;
- (3) how is uncertainty addressed in their model; and
- (4) what data inputs (source, date) do they use in their models and what are the limitations in these data.

The Contractor shall incorporate information obtained from modeling groups into the background paper.

#### ***Deliverable 4.1: Memoranda summarizing information obtained from modeling groups***

### **4.2: Develop In-Depth Material for economic projections in IAM/IAV Models and Uncertainty**

The EPA WAM provided preliminary reviews of the draft report content developed under the previous work assignment. Sections were identified that required additional technical development and reviews, specifically in the areas of economic projections in the IAM/IAV context and uncertainty.

Unlike Task 4.1 above, the in-depth material for IAM/IAVs should reflect community viewpoints, not specific modeling groups. The Contractor shall develop written material based on a limited number of community-level resources such as the Energy Modeling Forum and the Integrated Assessment Modeling Consortium. Current directions and developments shall be discussed as part of this in-depth material. The Contractor shall consult with at least one recognized IAM/IAV community expert to provide guidance and reviews of the material.

There is a very large literature with respect to uncertainty in economic and IAM/IAV modeling. The Contractor shall not conduct a comprehensive review of the uncertainty literature, but rather rely on a limited number of sources such as those noted above. The Contractor shall focus on a relatively small number of key points, consulting with experts in this area to discuss ways that uncertainty for these types of models could be systematically evaluated.

***Deliverable 4.2: Memoranda summarizing findings from in-depth investigation of economic projections in IAM/IAV models and uncertainty***

**4.3: Prepare revised draft report**

The Contractor shall prepare a revised draft report, incorporating material from Tasks 4.1 and 4.2. The Contractor shall also revise other sections as needed to ensure appropriate coverage of the scientific literature, the impact assessment literature, and additional economic variables beyond GDP. The Contractor shall arrange for an internal review of the draft report to ensure it is appropriately focused for the target audience.

***Deliverable 4.3: Revised draft report***

**Task 5: Attend experts meeting and incorporate independent expert views into the draft report and prepare final report.**

The Contractor shall attend a small experts meeting, participating in discussions, taking notes and preparing a short summary which captures the individual views of the experts in attendance. The summary shall include key discussion points with respect to near-, medium- and long-term modeling issues and capabilities, research needs, and potential for developing scenario products for the USGCRP. The summary shall be appended to the background report, with key points captured in the report's Executive Summary.

The Contractor shall arrange for an internal review and technical edit of the draft report to ensure it is suitable for dissemination to meeting attendees and SISCAG. The Contractor shall revise the report and respond to comments on the workshop report from EPA, DOE, USGCRP, and attendees. The Contractor shall prepare a final report for EPA clearance and posting to the USGCRP web-site.

***Deliverable 5: Final report***

**IV. ANTICIPATED DELIVERABLES**

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [\*.d), \*.out, \*.opt, \*.ssn]).

**V. DELIVERABLES AND SCHEDULE**

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award of Work Assignment
Task 3. Finalize website content	2 weeks after receipt of WAM comments
Task 4.1 Memoranda summarizing information obtained from modeling groups	8 weeks after award of Work Assignment
Task 4.2 Memoranda summarizing findings from in-depth investigation of economic projections in IAM/IAV models and uncertainty	10 weeks after award of Work Assignment
Task 4.3 Revised draft report	3 weeks before the experts meeting
Task 5. Final report	6 weeks after experts meeting



Note: All days are calendar days.

## **VI. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

## **VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

## **VIII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

## **IX. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

### **Work Assignment Manager (WAM)**

Anne Grambsch  
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Washington, DC 20460  
(703) 347-8521; FAX (703) 347- 8694  
[grambsch.anne@epa.gov](mailto:grambsch.anne@epa.gov)

### **Alternate Work Assignment Manager (WAM)**

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U.S. EPA  
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Washington, DC 20460  
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## Appendix A

### Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

**FOCUS:** the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

**VERIFY:** the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

**INTEGRITY:** Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

**RIGOR:** the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

**UTILITY:** the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

**CLARITY:** Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

## **DATA CHECKLIST FOR EVALUATING A STUDY**

1.) Bibliographic identification of the study.

Study Identifiers:

Author(s):

Title:

Study Citation:

Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-53

☐ Other ☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base

Option Period Number 2

Title of Work Assignment/SF Site Name

Economic Scenarios and Valuation

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

See comments

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/12/2015 To 10/31/2016

Comments:

B. Risk Assessment Methods Research and Development

D. Analysis, Document and Issue Paper Preparation

E. Risk Assessment Support: 1. Science Writing, Risk Communication and Training

G. Literature Search



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:

11/01/2013 To 10/31/2016

Cost/Fee: \$0.00

LOE: 0

This Action:

\$149,817.00

1,017

Total:

\$149,817.00

1,017

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

12/02/2015

Cost/Fee:

\$149,817.00

LOE: 1,017

Cumulative Approved:

Cost/Fee:

\$149,817.00

LOE: 1,017

Work Assignment Manager Name Anne Grambsch

(Signature)

(Date)

Branch/Mail Code:

Phone Number 703-347-8521

FAX Number:

Project Officer Name Melissa Revelly-Wilson

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-55				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number      2			Title of Work Assignment/SF Site Name NCEA Public Scientific Worksho				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW A. Assessment Issues and Documents					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/05/2015   To   10/31/2016				
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund         <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund       </div>										
Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
SFO <input type="checkbox"/> (Max 2)										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
11/01/2013   To   10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:				Cost/Fee:			LOE:			
Cumulative Approved:				Cost/Fee:			LOE:			
Work Assignment Manager Name   Joe DeSantis  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number   703-347-8616 FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name   Adam Meier  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107			

**PERFORMANCE WORK STATEMENT**  
**Contract No. EP-C-14-001**  
**WA 2-55**

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**Title:** NCEA Public Scientific Workshops 2016

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**Specify Section & Paragraph SOW:** A. Assessment Issues and Documents

**PERIOD of PERFORMANCE:** CO Award – October 31, 2016

**I. PURPOSE**

The purpose of this work assignment is to provide administrative and logistical support to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) for up to three public scientific workshops to be held, or planned, between December 2015 and October 31, 2016. The workshops will be held in EPA conference space at Potomac Yard One, 2777 S. Crystal Drive, Arlington, VA 22202, or in commercial conference space arranged by the contractor. The workshops will focus on cross cutting scientific issues related to the development of health assessments of chemicals present in the environment. EPA will specify the general topics for each workshop approximately 2 - 3 months before each workshop. EPA will release workshop materials before each workshop. The purpose of the workshops is to provide an opportunity for recognized experts to provide input and engage in a dialogue with EPA on state-of-the-science approaches for addressing scientific issues of key importance to developing health assessments of environmental pollutants.

**II. BACKGROUND**

EPA's National Center for Environmental Assessment (NCEA), located in the Office of Research and Development, is a leader in the science of human health and ecological risk assessment, a process used to determine how pollutants or other stressors may impact human health and the environment. The center occupies a critical position in EPA's Office of Research and Development (ORD) between researchers in other parts of ORD and outside of EPA who are generating new findings and data and the regulators in EPA's program and regional offices who must make regulatory, enforcement, and remedial action decisions.

NCEA addresses the needs of stakeholders by preparing technical reports and assessments that integrate and evaluate the most up-to-date research. These products serve as a major component of the scientific foundation supporting EPA's regulations and policies. NCEA also conducts cutting-edge research to develop innovative quantitative risk assessment methods and tools that help extrapolate between experimental data and real-world scenarios, improve our understanding of uncertainties, and facilitate careful weighing of evidence.

NCEA develops a broad range of assessment materials that are used by the EPA media programs, State and local environmental agencies, and the public and private risk assessment community. These materials include integrated science assessments (ISA) for the six criteria air pollutants (carbon monoxide, lead, ozone, particulate matter, nitrogen oxides and sulfur) in support of National Ambient Air Quality Standards (NAAQS) decision-making. The Integrated Risk Information System (IRIS) program is also housed within NCEA. The IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. When supported by

available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). NCEA also develops methods to assess human health and ecological risks associated with environmental pollutants.

The workshops will be held on the dates to be specified by EPA. Materials for the workshops will be posted on the IRIS website (<http://www.epa.gov/iris/publicmeeting/>). The workshops provide an opportunity for the recognized national experts to provide input on major scientific issues concerning the development of assessments. Workshop topics may include cross cutting issues such as data emerging technologies, evaluating and communicating uncertainty and variability, tools for quantifying cumulative exposure such as epigenetics, biomarkers, and toxicogenomics, application of NexGen principles, and chemical specific issues related to interpretation, analysis and/or modeling of toxicological data for highly complicated major assessments.

While the workshops will be open to the public and stakeholders and questions and comments will be entertained, the focus of the workshops will be input from recognized national (and international) experts who are active in research and/or assessment activities related to the workshop topics.

### **III. STATEMENT OF WORK**

#### **A. Objective**

The overall objective of this work assignment (WA) is to provide administrative and logistical support for up to three public workshops to be held, or planned, between December 2015 and October 31, 2016. This support includes identifying national and international experts, scheduling their participation, arranging for appropriate compensation for the experts, arranging transportation and lodging and providing other logistical support to facilitate their participation in the workshop, formulating the workshop agenda, workshop registration, preparation and distribution of workshop materials, meeting facilitation, onsite registration and other general logistical support before, during and after the workshop. The workshops will be held in EPA conference space at the Potomac Yard One Conference Facility on 2733 S. Crystal Drive, Arlington, VA 22202, or in commercial conference space arranged by the contractor. The workshops shall include access by webinar and teleconference lines. Stakeholders and members of the public will be invited to attend and may have an opportunity to ask questions or participate in an open dialogue on the scientific issues. The Contractor shall provide assistance (including onsite assistance) to EPA prior to, during, and after the workshops. Administrative and logistical support shall consist of the following tasks:

#### **B. Specific Requirements (Tasks)**

- 1. Establish Communication** Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.



## **2. Support Provided Before the Workshops**

- a. Identify and contact non-federal and federal subject matter experts who a) are recognized experts in the field(s) and issues relevant to the workshop, b) represent a range of recognized views on the issues identified by EPA, and c) are available to present and discuss their research and individual views at the public workshop. Experts with an understanding of chemical hazard assessment are generally preferred.
- b. Identify a sufficient number of candidate experts, for consideration by EPA, to allow the selection of up to 3-5 experts per issue to be discussed at the workshop. The total number of experts to be provided for each workshop will average between 10 to 20 experts for each workshop. The contractor must provide bio-sketches to EPA for assessing the expert's qualifications and for posting on the EPA website for those experts selected to participate in the workshop.
- c. Arrange appropriate compensation (e.g., honoraria) for the time and effort of the non-federal experts. The Contractor shall arrange and provide for transportation, lodging, and logistical support for experts asked to participate in panel discussions, or pre-workshop planning or seminar sessions, which will be held on site in Arlington, VA., or in commercial conference space arranged by the contractor, or via webinar. Experts not serving in panel discussions, or unable to travel, may participate by webinar.
- d. If directed by the WAM, arrange for participation of expert(s) in pre-workshop planning or seminar sessions, including webinars, to help formulate the workshop agenda and/or facilitate the participation of attendees in the workshop.
- e. Establish and monitor a registration website for each workshop and compile and maintain the workshop registration list. Provide updated registration lists to EPA on a weekly basis after registration opens and more frequently when registration deadlines are approaching.
- f. Manage the collection of the experts' presentations and prepare electronic files needed during the workshop. Load all expert and EPA presentations on the computer to be used during the workshop.
- g. If commercial conference space is used, make arrangements for AV and IT support to ensure adequate telephone and internet connections and webinar meeting room space will be available at the meeting location. If EPA conference space is used, coordinate with EPA AV and IT support to ensure adequate telephone and internet connections and webinar room space will be available.
- h. Make copies of the meeting agenda, and other routine meeting materials for distribution on the meeting dates as directed by the EPA WAM.
- i. For workshops held in EPA conference space, provide EPA security, or the EPA WAM, a list of non-EPA attendees no less than two days before the workshop.
- j. Make arrangements for and staff a sign-in table/reception area at the workshop location for both EPA and commercial locations.

- k. Conduct up to two dry-runs prior to each workshop including the webinar and physical room set-up, operation of all AV equipment, internet connections, cameras, and computer equipment, and presentations to be used at the workshops.

### **3. Support Provide During the Meetings**

- a. Make arrangements for and staff sign-in table/reception area during the meeting. Provide general workshop support materials such as sign-in sheets, name tags and name tents, placement of meeting signs, and organization and functioning of the reception area.
- b. Provide on-site meeting facilitation to promote adherence to the schedule and agenda, and a balanced opportunity for panelist to participate. This includes introduction of panel members, management of public question and comment periods throughout the workshop including from those in the room, via webinar, and teleconference line, and specification of workshop procedures. The contractor will monitor webinar and teleconference questions, read webinar questions to the meeting room at appropriate times during the workshop, and introduce teleconference questions at appropriate times during the workshop, to ensure a smooth transition between speakers and issues.
- c. If commercial space is used, address technical difficulties raised by webinar participants and address all audio/video issues that may arise. If EPA space is used, assist EPA in addressing technical difficulties raised by webinar participants, and in addressing audio/video issues.
- d. If commercial space is used establish teleconference line connection and webinar room no later than 30 minutes before the workshop begins.

### **4. Support After the Meetings**

- a. Provide final registration and attendees lists, both EPA and non-EPA.
- b. If directed by the WAM, provide a limited meeting summary including the general content of presentations, comments on the science questions discussed, panel discussions and recommendations.
- c. Provide webinar poll results, if any.

## **IV. SCHEDULE OF DELIVERABLES**

<b>Deliverable</b>	<b>Due Dates</b>
1. Teleconference NTE 1 hr - outlining how all tasks shall be performed.	Within 3 days of award
2. Submit list of candidate experts to participate in the workshop to the EPA WAM	2 months before each workshop

3. Establish workshop registration website	2 months before each workshop
4. Assist in the development of the workshop agenda including preparation of the agenda for posting to the EPA website.	1 -2 months before each workshop
5. Provide registration updates	Weekly after registration opens and more frequently when registration closure approaches
6. Submit final list of experts to participate in the workshop to the EPA WAM	1 month before the workshop
7. Respond to registrant questions and organize expert coordination meetings if requested by EPA WAM	From date registration opens to date of workshop
8. Complete arrangements for lodging, transportation, and other logistical support for experts attending workshop	1 month before the workshop
9. Submit experts' presentations to the EPA WAM	2 weeks before each workshop
10. Participate in up to two dry runs of each workshop.	Within 1-2 weeks before each workshop
11. For workshops held in EPA conference space, submit final list of registered attendees to EPA security	No later than 2 days before each workshop
12. Staff and organize sign-in table and reception area, and provide name tags, name tents, and other routine meeting materials.	Workshop meeting days
13. Facilitate meeting – introduce discussants, maintain schedule, transition between issues, bring up presentations, coordinate webinar and teleconference questions, read webinar questions to the room	Workshop meeting days
14. Provide registration/attendance list, webinar statistics and poll results, if any.	Within 1 week after each meeting
15. Provide limited summary proceedings if directed by the WAM	Within 30 days of workshop conclusion

## **V. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

**EPA GREEN MEETING REQUIREMENTS:** When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green

Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at <http://www.epa.gov/oppt/greenmeetings/>.

## **VI. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Joe DeSantis

703-347-8616

[desantis.joe@epa.gov](mailto:desantis.joe@epa.gov)

Work Assignment Form. (WebForms v1.0)

Work Assignment Form. (WebForms v1.0)

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**Work Assignment Number  
2-55☐ Other ☒ Amendment Number:  
000002Contract Number  
EP-C-14-001Contract Period 11/01/2013 To 10/31/2016  
Base Option Period Number 2Title of Work Assignment/SF Site Name  
WA 2-55 NCEA WorkshopsContractor  
ICF INCORPORATED, L.L.C.Specify Section and paragraph of Contract SOW  
Section B.4Purpose: ☐ Work Assignment  
☒ Work Assignment Amendment  
☐ Work Plan Approval☐ Work Assignment Close-Out  
☐ Incremental Funding

Period of Performance

From 11/05/2015 To 10/31/2016

Comments:  
Additional effort needed to produce workshop report/journal article.☐ Superfund

## Accounting and Appropriations Data

☒ Non-SuperfundSFO  
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:  
11/01/2013 To 10/31/2016

Cost/Fee:

LOE:

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee

LOE:

Cumulative Approved:

Cost/Fee

LOE:

Work Assignment Manager Name Vicki Soto

Branch/Mail Code:

Phone Number: 703-347-0290

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name Gina Perovich

Branch/Mail Code:

Phone Number: 703-347-8656

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT**  
**Contract No. EP-C-14-001**  
**WA 2-55 Amend 2**

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**Title:** NCEA Public Scientific Workshops 2016

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**Specify Section & Paragraph SOW:** A. Assessment Issues and Documents

**PERIOD of PERFORMANCE:** CO Award – October 31, 2016

The purpose of this modification is to add the following task:

**1. Support After the Meetings**

- a. Provide final registration and attendees lists, both EPA and non-EPA.
- b. If directed by the WAM, provide a limited meeting summary including the general content of presentations, comments on the science questions discussed, panel discussions and recommendations. For the Temporal Exposures Workshop (1/27-1/29/16), provide a workshop summary written as a journal article to be published in Environmental Health Perspectives or a similar peer-reviewed journal. In order to provide a report that includes background information, the following subtasks should be provided:
  - 1) Create detailed outline
  - 2) Research references provided by presenters – including additional references solicited after the workshop.
  - 3) Research websites of state/federal agencies that might inform on the workshop topic.
  - 4) Summarize presentation content
  - 5) Incorporate discussions from the panels as appropriate
  - 6) Summarize methodologies presented at the workshop and research further for a complete summary
  - 7) Show methods in a table view
  - 8) summarize future research needs
  - 9) contact presenters, if necessary, for further information or follow-up
  - 10) Draft article, provide in format suitable for submission to a peer-reviewed journal. Document should be edited and formatted per journal style as appropriate and should include formatted bibliography. It should be submitted for EPA (and other reviewer) comments
  - 11) Revise drafted article based on EPA comments



<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-55			
						<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000002			
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number      2			Title of Work Assignment/SF Site Name NCEA Public Scientific Worksho			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW A. Assessment Issues and Documents					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval				Period of Performance  From   11/05/2015   To   10/31/2016					
Comments:									
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		\$149,650.00		LOE:		952	
11/01/2013 To 10/31/2016									
This Action:				\$13,618.00				167	
Total:				\$163,268.00				1,119	
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:		04/16/2016		Cost/Fee		\$13,618.00		LOE: 167	
Cumulative Approved:				Cost/Fee		\$163,268.00		LOE: 1,119	
Work Assignment Manager Name   Vicki Soto  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number:		703-347-0290	
						FAX Number:			
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number:		919-541-0207	
						FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number:			
						FAX Number:			
Contracting Official Name   William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code:			
						Phone Number:		513-487-2055	
						FAX Number:			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-56			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001		Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number    2		Title of Work Assignment/SF Site Name Toxicity Reference Database					
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW C. Risk Assessment Data Bases and Computer Tools					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2015   To   10/31/2016			
Comments:									
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO <input type="checkbox"/> (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
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4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:		LOE:					
11/01/2013   To   10/31/2016									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:		Cost/Fee:		LOE:					
Cumulative Approved:		Cost/Fee:		LOE:					
Work Assignment Manager Name   Sandra Roberts  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number   919-541-3850 FAX Number:		
Project Officer Name   Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number:   703-347-8523 FAX Number:   703-347-8696		
Other Agency Official Name  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number: FAX Number:		
Contracting Official Name   Adam Meier  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>							Branch/Mail Code: Phone Number:   513-487-2852 FAX Number:   513-487-2107		

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-56**

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**TITLE:** Technical Support for Curation of Toxicity Reference Database (ToxRefDB)

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**Specify Section & Paragraph SOW:** C. Risk Assessment Data Bases and Computer Tools

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**PERIOD of PERFORMANCE:** CO approval through 10/31/2016.

**I. PURPOSE.**

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Computational Toxicology (NCCT) to curate available legacy toxicity information on repeat-dose short-term and long-term toxicity studies into the Toxicity Reference Database (ToxRefDB).

**II. BACKGROUND AND OBJECTIVES.**

The National Center for Computational Toxicology (NCCT) is responsible for developing computational tools and solutions for improving environmental risk assessments and regulatory decisions. NCCT is developing methodologies to characterize chemicals based on known and predicted toxic effects. As a part of this effort, the NCCT's ToxRefDB project (<http://epa.gov/ncct/toxrefdb/>) has compiled thousands of in vivo animal toxicity studies on hundreds of chemicals. ToxRefDB supports NCCT's ToxCast project by providing in vivo data to anchor in vitro and in silico models while also serving as a public reference tool.

**III. STATEMENT OF WORK.**

The contractor shall be responsible for completion of three tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

**Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Work Assignment Contracting Officer's Representative (WA COR).**

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

**Deliverable 1:** The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

**Task 2. The contractor shall review the accuracy of the ToxRefDB study file with the associated study report(s) including capturing the testing status for all observations**

The ToxRefDB stores roughly 6000 animal toxicology studies in a relational database with controlled vocabularies. Over 1000 chemicals have at least one study in the database. A subset of these studies, roughly 3000, have NOAEL/LOAEL determinations. For each LOAEL, a set of effects were assigned to the LOAEL as being critical. The LOAELs and associated effects have all been entered and tagged in the database previously.

The contractor shall assist EPA in reviewing the LOAELs and associated effects for accuracy in the database to ensure the quality of the following tasks as well as catalog the testing status of all observations (e.g., tested, not tested, not reported). The contractor shall provide a monthly summary of the studies reviewed and any edits performed.

1. Specifically, the contractor will open the source study documents, housed at the EPA, and compare stated NOAEL/LOAEL levels in the documents with levels listed in the ***ToxRefDB outputted file(s)***. The critical effects ***and all other treatment-related effects*** listed can be compared and reviewed in a similar manner. The EPA estimates the review process to take roughly 30 minutes per study, on average.
2. Additionally, the contractor shall capture the testing status of all study observations provided for in the ***ToxRefDB outputted file(s)***. The EPA estimates the review process to take roughly 30 minutes per study, on average.

**Deliverable 2:** The contractor shall provide a **monthly** summary of the studies reviewed and any edits performed.

### **Task 3. The contractor shall enter quantitative data for all effects.**

The NOAEL/LOAEL determinations and the associated critical effects have been entered and quality controlled (task 2) ***as well as all other treatment-related effects*** in ToxRefDB. With the goal of performing dose-response modeling (benchmark dose modeling) to determine more quantitative points of departure, the contractor shall enter the dose-response data (incidence and/or mean +/- standard deviation, and sample size, ***as well as any other necessary fields mutually decided***) for each treatment group, including the control group, for all effects tagged ***treatment-related and/or critical*** in the study.

For example, a study was run at 3 doses plus controls with male and female groups. The NOAEL was established at 10 mg/kg/day and the LOAEL at 100 mg/kg/day based on liver weight gain in males and females, liver hypertrophy in males and females, and thyroid hyperplasia in the males. Additionally, spleen weight increase was observed and deemed treatment-related in the high dose group at 1000 mg/kg/day. With this example, the contractor shall enter the group mean and standard deviation for liver and spleen weights and incidence information for liver hypertrophy and thyroid hyperplasia at each dose level and for the control group(s).

The EPA estimates the primary data extraction to take roughly 2 hours per study, on average, with a secondary review taking 1 hour per study on average.

**Deliverable 3:** The contractor shall provide the COR with a monthly summary of the number of studies with completed quantitative data entry as well as any specific comments regarding special cases or anomalies with data entry.

## **IV. SUMMARY TIME TABLE.**

Task	Deliverable	Time frame
1	Establish communication via conference call	Within 1 week after receipt of work assignment

2	Monthly summary of studies reviewed	Monthly
3	Monthly summary of studies with quantitative data entered	Monthly

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA WA COR.
3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.
4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

## **V. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignments reports stipulated in contract.

## **VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the WA COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

## **VII. EPA CONTACT INFORMATION.**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the Work Assignment Contracting Officer's Representative (WA COR).

<b>WA COR</b> Matthew Martin National Center for Computational Toxicology Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (B205-01) RTP, NC 27711 Telephone #: (919) 541-4101	<b>Alternate WA COR</b> Sandra Roberts National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency 109 T.W. Alexander Dr. (B205-01) RTP, NC 27711 Telephone #: (919) 541-3850
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FAX #: (919) 541-1194  
Email: [martin.matt@epa.gov](mailto:martin.matt@epa.gov)

FAX #: (919) 541-1194  
Email: [roberts.sandra@epa.gov](mailto:roberts.sandra@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-56			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base                      Option Period Number    2			Title of Work Assignment/SF Site Name Toxicity Reference Database			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW C. Risk Assessment Data Bases and Computer Tools					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval				Period of Performance  From 11/01/2015 To 10/31/2016					
Comments:									
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO <input type="checkbox"/> (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee: \$0.00		LOE: 0					
11/01/2013 To 10/31/2016									
This Action:		\$19,273.00		1,381,845					
Total:		\$1,378,845.00		19,273					
Work Plan / Cost Estimate Approvals									
Contractor WP Dated: 11/20/2015		Cost/Fee \$19,273.00		LOE: 1,381,845					
Cumulative Approved:		Cost/Fee \$1,378,845.00		LOE: 19,273					
Work Assignment Manager Name    Sandra Roberts  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number: 919-541-3850 FAX Number:			
Project Officer Name    Melissa Revelly-Wilson  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:			
Other Agency Official Name  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Adam Meier  <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107			

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-60			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001			Contract Period   11/01/2013   To   10/31/2016 Base                      Option Period Number      2			Title of Work Assignment/SF Site Name Particulate Matter			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW A. Assessment Issues and Documents					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From   11/01/2015   To   10/31/2016			
Comments:									
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO (Max 2) <input type="checkbox"/>									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:			LOE:				
11/01/2013   To   10/31/2016									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:			Cost/Fee:			LOE:			
Cumulative Approved:			Cost/Fee:			LOE:			
Work Assignment Manager Name    Ellen Kirrane  <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between; font-size: small;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number    919-541-1340 FAX Number:			
Project Officer Name    Melissa Revely-Wilson  <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between; font-size: small;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number:    703-347-8523 FAX Number:    703-347-8696			
Other Agency Official Name  <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between; font-size: small;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number: FAX Number:			
Contracting Official Name    Adam Meier  <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between; font-size: small;"> <span>(Signature)</span> <span>(Date)</span> </div>						Branch/Mail Code: Phone Number:    513-487-2852 FAX Number:    513-487-2107			



**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-60**

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**TITLE: Integrated Science Assessment for Particulate Matter: Authorship of Specific Sections**

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**Principal Section & Paragraph of SOW: A. Assessment Issues and Documents**

**PERIOD OF PERFORMANCE: CO Approval – October 31, 2017**

**I. PURPOSE**

The purpose of this work assignment is to manage qualified scientists to author specific sections of the Integrated Science Assessment (ISA) for Particulate Matter (PM). This work assignment shall be conducted for the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) and is consistent with the purpose and scope of Contract EP-C-14-001.

**II. BACKGROUND**

Sections 108 and 109 of the Clean Air Act require periodic review and, if appropriate, revisions of the national ambient air quality standards (NAAQS) and the air quality criteria on which they are based. EPA initiated a review of the NAAQS for PM in December of 2014. The Agency held a workshop in February of 2015 to receive input from internal and external PM experts regarding the current and emerging science. The Agency will consider the issues that were raised at that workshop as it develops the draft integrated plan and develops the NAAQS technical support documents, which incorporate the most current, policy relevant science. The Agency now seeks to recruit expert scientists to author specific sections of the ISA, which is a review, synthesis and evaluation of the most policy-relevant evidence. The ISA communicates the critical science judgments relevant to the NAAQS review. The first external review draft (ERD) of the ISA is tentatively scheduled for release in December of 2016 and the second ERD is tentatively scheduled for release in the fall of 2017.

**III. STATEMENT OF WORK**

**TASK 1 - Establish Communication**

Within 3 days of award of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan for proposing a technical approach to the work assignment. The work plan shall outline how the work shall be performed and provide a list of deliverables and interim deliverables with the schedule for completion. In addition, the budget and staffing plan and a brief description of the qualifications of the key technical staff shall be included. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person or by phone) between the Contractor and WAM to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

## **TASK 2 – PREPARE A QUALITY ASSURANCE PROJECT PLAN (QAPP)**

The Contractor can update the existing Quality Assurance Project Plan (QAPP) developed for WA 1-60 (ICF Ref #130619.1.060.00 Quality Assurance Project Plan Integrated Science Assessment for Particulate Matter: Authorship of Specific Sections signed April 27, 2015). This QAPP should be updated to document the quality processes and procedures for applicable tasks described in this Task Order and submit the QAPP for EPA TOPO approval and QA Manager approval. The Contractor shall not perform any work on the new tasks under this Task Order until the QAPP is reviewed and approved by the EPA TOPO and QA Manager. The QAPP shall include documentation on quality assurance checks to verify accuracy, completeness, and adherence to established format. The QAPP shall also document the literature search strategy and address the use of existing (second and third party) data to carry out this Task Order. The Contractor must address in the QAPP how they are going to consider the use of existing data to carry out this task. Existing data are defined as environmental or health data that were developed for a different purpose.

Guidance for developing QAPPs that meet EPA specifications prepared for activities conducted by or funded by EPA, are available online at <http://www2.epa.gov/quality/agency-wide-quality-system-documents>, see “*EPA Manual CIO 2105-P-01-0: EPA Quality Manual for Environmental Programs* (2000)”; “*EPA/240/B-01/003: EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (2001)”; “*EPA 100/B-03/001: A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (2003),” and the addendum, “*Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information* (2012).”

## **TASK 3 – MANAGE, IDENTIFY AND RECRUIT EXPERT AUTHORS**

The Contractor shall recruit and manage expert scientists in the completion of sections of the PM ISA (deliverables under WA 1-60 (Contract NO. EP-C-14-011). EPA will provide written comments on sections delivered under WA 1-60. The Contractor shall provide ISA sections to the expert authors, along with written comments provided by EPA. The objective of the work assignment is to incorporate EPA comments, update with new literature and complete draft ISA sections that generally conform to the style and the form of the ISA. The Contractor shall be responsible for ensuring communication between the EPA work assignment manager (WAM) and the authors so that technical clarification can be offered and interaction between authors can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

The topics of the sections to be authored includes the following:

- Task 5 Epidemiology: PM Exposure and Respiratory Effects
  - 5a. Short-term exposure and hospital admissions/emergency department visits
  - 5b. Long-term exposure and respiratory morbidity effects
- Task 6 Epidemiology: PM Exposures and Cardiovascular and Related Metabolic Effects
  - 6a. Short-term exposure and hospital admissions/emergency department visits
  - 6b. Short-term exposure and CVD morbidity effects
  - 6c. Long-term exposure and CVD morbidity effects
- Task 7 Epidemiology: Short-term PM Exposures and Mortality
- Task 8 Epidemiology on the Carcinogenic Effects of PM
- Task 9 Respiratory and Immune System Toxicology
- Task 10 Particle Translocation from Respiratory Surfaces and Modifying Factors
- Task 11 Controlled Human Exposure Studies of Respiratory and Immunological Effects
- Task 12 Cardiovascular Toxicology

- Task 13 Controlled Human Exposure Studies of Cardiovascular Effects
- Task 14 Toxicological studies of Cancer, Genotoxicity, Epigenetics, and Mutagenicity
- Task 15 Reproductive and Developmental Toxicology
- Task 16 Visibility Effects
- Task 17 PM Modeling and Data Fusion for Exposure Assessment
- Task 18 Sources, Chemistry, Nucleation, Measurement, Concentrations, and Spatial Variability of Ultrafine Particles
  - 18a. Sources of Ultrafine Particles
  - 18b. Chemistry of Ultrafine Particles
  - 18c. Nucleation of Ultrafine Particles
  - 18d. Measurement of Ultrafine Particles
  - 18e. Concentrations of Ultrafine Particles
  - 18f. Spatial Variability of Ultrafine Particles
- Task 19 Radiative Forcing and Climate Effects of PM

Details relevant to the written sections on each of these topic areas are discussed under Tasks 5-19 below. The Contractors shall recruit and manage the expert authors who shall update the respective sections of the ISA delivered under WA 1-60 (Contract NO. EP-C-14-011).

The EPA assumes primary authorship in the writing process and contributing authors are listed in the final document as appropriate. EPA will approve (or disapprove) each of the expert authors performing this work within two days of notification of a potential candidate.

To successfully complete *Task 3*, the Contractor shall perform the following subtasks:

### **Subtask 3a – Identify and Recruit Expert Scientists**

The Contractor shall identify and contact experts with a knowledge base that is aligned with the description in Task 5-18. The Contractor shall provide a list of expert authors within 3 days of workplan approval for review and confirmation by EPA. The Contractor shall submit a bio-sketch for any expert authors that have not contributed to the draft sections delivered under WA 1-60 (Contract NO. EP-C-14-011).

### **Subtask 3b - Manage Expert Scientist Authors**

The Contractor shall manage the expert scientists that are identified and recruited to author sections of the ISA and ensure communication between EPA and the authors. This shall involve setting up approximately 6-10 conference calls with authors and EPA staff in preparation of final draft sections. In addition, the Contractor shall ensure that the responses to EPA comments provided upon the review of deliverables from WA 1-60 (Contract NO. EP-C-14-011) are addressed and the finalization of sections are progressing on schedule and are delivered by the deadlines noted in this WA.

## **TASK 4 –MANAGE LITERATURE SEARCH AND TABULATE STUDY INFORMATION**

EPA has conducted an exhaustive literature search on PM and health effects and will make the literature search results available to the Contractor in HERO (Health and Environmental Research Online). The HERO database contains all studies identified through EPA's literature search strategy. The broad literature search identified hundreds of thousands of studies that have been topic classified into specific scientific discipline categories (e.g. epidemiology and experimental). The studies identified may be exported into an Endnote library as needed. The

Contractor (and expert authors) shall have access to the study PDFs and if needed can request access to other PDFs relevant to the sections being updated.

To successfully complete *Task 4*, the Contractor shall perform the following subtasks:

### **Subtasks**

#### **(1) Coordinate HERO Access and Training**

The Contractor shall provide HERO access to expert authors and relevant personnel by sending an email to [hero@epa.gov](mailto:hero@epa.gov) and including the following information: name, mailing address, phone number, and email address of the authors and other personnel needing HERO accounts as well as the project name, start date and end date. EPA will provide the Contractor with HERO account information, with user documentation, within 3 business days. The Contractor shall provide training on the use of HERO tools as needed.

#### **(2) Update List of New References (potentially considered literature)**

Databases (e.g., Endnote Libraries) containing results from the broad literature search described above, and covering the period (1/2008-12/2014), were provided to the Contractor under WA 1-60. EPA will provide an updated database that will include references from 12/2014 through 11/1/2015 within 5 days of the workplan acceptance.

The Contractor and/or expert author shall search databases, specifically either the experimental or epidemiology categories for PM, to create a list of new references relevant to a specific endpoint and discipline. New literature is defined as literature published since January of 2008; however, policy-relevant articles published prior to that date and detailed in previous assessments shall be included if appropriate to fully capture the current state of the science.

#### **(3) Update List of Considered References**

Once a preliminary list of new references is identified the Contractor (in consultation with expert author) shall review the title only to determine whether additional references, based on the updated literature search, shall be “considered” for inclusion in the ISA. “Considered” references are defined as all references that require more than the title to be read in order to determine whether it may be “included” in the ISA. The Contractor and/or expert author shall keep a list of all HERO ID numbers for all references that fall within this “considered” category. The Contractor and/or expert author shall then search through the list of “considered” references and identify a subset of references (by HERO ID) that potentially may be included in the ISA and fall within the scope of the PM ISA as detailed in Attachment 1. The Contractor shall perform additional literature searches outside of HERO as needed if specific references that the Contractor is aware of have not been identified during EPA’s broad literature search. If the Contractor conducts additional literature searches outside of HERO the Contractor shall maintain a list of databases searched and key words used.

#### **(4) Update Data Tables**

The Contractor (and/or expert author) shall update and revise, based on feedback from EPA, the tables provided as an attachment for each of the studies included in the epidemiology and experimental sections. For the epidemiologic studies, the study-specific details to be extracted from the studies include but are not limited to the study location, key effect estimates, effect measure modifiers examined. For experimental data, the study specific details to be extracted include study reference,

animal/human volunteer characterization (e.g., number, age, sex, strain, race etc.), PM characterization (e.g., particle size and concentration), exposure protocol, main endpoints. An example of the information to be included in each spreadsheet for the epidemiology sections is found in Attachment 2.

Where the data extraction requires expert input (e.g. where multiple effect estimates are reported in a study) EPA will offer technical guidance. Depending on the complexity of the study, expert authors shall also contribute to the extraction as needed. The contribution of expert authors shall include but not be limited to decisions regarding the selection of results presented in the tables and the text and how study results are characterized, in the tables produced for the experimental studies. Several examples to guide in selection of epidemiologic study results are below:

- a.) For short-term exposure studies, the selection of key effect estimates to discuss when detailing the results of a study should follow the following hierarchy:
  - i. Distributed lag
  - ii. Average of multiple days (e.g., 0-2)
  - iii. If *a priori* days were used by the study authors these are the effect estimates that should be presented
  - iv. If individual lag days presented select the most significant
- b.) Where stratified effects or interactions are presented, extract the main effect. If stratified results are also reported, note that results should be included in the at-risk chapter and list those categories by which results are presented (e.g., sex, age, pre-existing disease, etc.). A column is designated in Attachment 2 where this type of information can be detailed.

## **TASK 5: PREPARE WRITTEN SECTIONS ON THE EPIDEMIOLOGIC EVIDENCE OF PM EXPOSURES AND RESPIRATORY EFFECTS**

There are two sub-sections of the section on short-term PM exposures and respiratory effects, which are described in Tasks 5a (short-term) and 5b (long-term).

### ***Task 5a. Short Term PM Exposures and Hospital admissions/Emergency department visits***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant scientific evidence on short-term PM exposures (i.e., exposures ranging from hours to weeks) and hospital admissions and emergency department (ED) visits based on literature available since completion of the previous PM ISA, while considering the new literature in the context of the older studies. The Contractor shall participate in telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the short-term PM exposures and hospital admissions and ED visits section of the PM ISA shall have research experience in air pollution epidemiology with a focus on examining the respiratory health effects associated with short-term air pollution exposures. Desirable experience includes examining: 1) potential copollutant confounding; 2) model specification; 3) lag structure of associations; and 4) concentration-response relationship of short-term air pollution exposures and hospital admissions and ED visits. The hospital admissions and ED visits author(s) shall have an MD or PhD and appropriate publication history (e.g. no fewer than 3 publications) and at least 3 years of experience researching and publishing on the association between short-term air pollution exposures and health effects. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s) and make final approvals.

To successfully complete *Task 5a*, the Contractor shall perform the following subtasks.

## **Subtasks**

### **(1) Literature Search**

The Contractor shall update the detailed literature search of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on short-term PM exposures and hospital admissions and ED visits. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

### **(3) Update and Revise Tables Containing Study Specific Details.**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

## ***Task 5b. Long-term PM Exposures and Respiratory Effects***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant scientific evidence on long-term PM exposures (i.e., exposures ranging from months to years) and respiratory effects based on literature available since completion of the previous PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in telephone meetings as needed with EPA staff and other PM ISA authors.

The author shall have expertise needed to effectively review the association between long-term PM exposures and respiratory effects. A qualified person shall have a Ph.D. in epidemiology or a related field with at least 3 years of experience studying the health effects of long-term air pollution exposures. Evidence as an expert in the field shall be demonstrated by a history of at least 2 peer reviewed publications. Potential author(s) shall be



asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s) and make final approval.

To successfully complete *Task 5b*, the contractor shall perform the following subtasks.

## **Subtasks**

### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on long-term PM exposures and respiratory effects. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

## **Task 6. PREPARE WRITTEN SECTIONS ON THE EPIDEMIOLOGIC EVIDENCE ON PM EXPOSURES AND CARDIOVASCULAR AND RELATED CARDIOMETABOLIC EFFECTS**

There are three sub-sections of the section on short-term PM exposures and cardiovascular and related cardiometabolic effects, which are described in Tasks 6a (short-term exposure and hospital admissions/emergency department visits), 6b (short-term exposure and CVD morbidity) and 6c (long-term exposure and CVD). In defining short- and long-term exposure studies, short-term exposure studies are those where the exposure is defined as hours, to days, to weeks; whereas, long-term exposure studies are defined as exposures ranging from months to years. Provided the criteria for evaluating an author(s)' expertise that are described below are met, one expert may write more than one subsection.

### **Task 6a. Short Term PM Exposures and Hospital admissions/Emergency department visits**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on short-term PM exposures (i.e., exposures ranging from hours to weeks) and cardiovascular-related hospital admissions and emergency department (ED) visits based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on the epidemiology of PM exposures and cardiometabolic and cardiovascular effects shall have a Ph.D. and experience researching and publishing on the association between short-term air pollutant exposures and cardiovascular effects. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the epidemiology of air pollution and cardiovascular effects. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 5a*, the Contractor shall perform the following subtasks.

### **Subtasks**

#### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on short-term PM exposures and respiratory hospital admissions and ED visits. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

#### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

#### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

#### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

### ***Task 6b. Short Term PM Exposures and Cardiovascular and Related Cardiometabolic Morbidity***



The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on short-term PM exposures (i.e., exposures ranging from hours to weeks) and cardiovascular and related cardiometabolic effects based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on the epidemiology of PM exposures and cardiometabolic and cardiovascular effects shall have a Ph.D. and research experience in cardiometabolic and/or cardiovascular effects of air pollution. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the epidemiology of air pollution and cardiovascular effects. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 6b*, the Contractor shall perform the following subtasks.

### **Subtasks**

#### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on short-term PM exposures and cardiovascular and related metabolic morbidity effects. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

#### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

#### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

#### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

### ***Task 6c. Long-term PM Exposures and Cardiometabolic and Cardiovascular Effects***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on long-term PM exposures (i.e., exposures ranging from months to years) and cardiovascular and related cardiometabolic effects based on literature available since completion of the 2009

PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on the epidemiology of PM exposures and cardiometabolic and cardiovascular effects shall have a Ph.D. and research experience in cardiometabolic and/or cardiovascular effects of air pollution. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the epidemiology of air pollution and cardiovascular effects. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 6c*, the Contractor shall perform the following subtasks. The Contractor shall provide preliminary written sections to EPA by October 15, 2015.

### **Subtasks**

#### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on long-term PM exposures and cardiovascular and related metabolic effects. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

#### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

#### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

#### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

### **Task 7. PREPARE WRITTEN SECTIONS ON THE EPIDEMIOLOGIC EVIDENCE ON SHORT-TERM PM EXPOSURES AND MORTALITY**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant scientific evidence from the epidemiological literature on the association between short-term PM exposures and mortality. Short-term exposure studies are those where the exposure is defined as hours, to days, to weeks. The contractor shall participate in telephone meetings with EPA staff and other PM ISA authors. The Contractor

shall organize the section by uncertainties and limitations as done in recent ISAs (see example from 2012 O<sub>3</sub> ISA – Attachment 5) based on the literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies.

The author shall have expertise needed to effectively review the association between short-term PM exposures and mortality. A qualified person shall have a Ph.D. in epidemiology with at least 3 years of experience studying the health effects of short-term air pollution exposures. Evidence as an expert in the field shall be demonstrated by a history of at least 2 peer reviewed publications in the field or as a contributing author on at least 2 EPA scientific assessments. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 7*, the contractor shall perform the following subtasks.

### **Subtasks**

#### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on short-term PM exposures and mortality. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

#### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

#### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

#### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

### **TASK 8 – EPIDEMIOLOGIC EVIDENCE ON THE CARCINOGENIC EFFECTS OF PM**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on the carcinogenic effects PM exposures based on literature available since

completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on the epidemiology of PM exposures and carcinogenic effects shall have a Ph.D. and research experience in cancer and air pollution. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the epidemiology of long-term PM exposure and cancer. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 8*, the Contractor shall perform the following subtasks.

### **Subtasks**

#### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) epidemiologic articles and reports through November 1, 2015 that provide data and information on carcinogenic effects of PM. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

#### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

#### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

#### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

## **TASK 9 – TOXICOLOGICAL EVIDENCE OF RESPIRATORY AND IMMUNOLOGICAL EFFECTS OF PM EXPOSURE**

### ***Task 9a. PREPARE WRITTEN SECTIONS ON TOXICOLOGICAL EVIDENCE OF RESPIRATORY AND IMMUNOLOGICAL EFFECTS OF PM EXPOSURE***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing the toxicological evidence of respiratory and immunological effects resulting from exposure to PM. As part of the

2009 PM ISA, Sections 6.3 and 7.3 described toxicological evidence of respiratory and immunological effects resulting from PM exposure. For respiratory effects, this included altered pulmonary function, airway hyperresponsiveness, pulmonary injury, altered epithelial barrier function, pulmonary oxidative stress, altered morphology, and/or altered lung development. For immunological effects, this included innate and adaptive immune responses such as inflammation, allergic sensitization and host defense. These areas should be included in the search of the literature for newer publications on PM. The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D., M.D., or equivalent and research experience in physiology, immunology, toxicology or other biological sciences relevant to respiratory or immunological effects of PM exposure. The ideal author(s) would have at least 10 publications related to the investigation of respiratory or immunological toxicology of inhaled PM. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 9a*, the Contractor shall perform the following subtasks.

### **Subtasks**

#### **(1) Literature Search**

The Contractor shall update the detailed literature survey of all new peer-reviewed, published (or accepted for publication) articles and reports through November 1, 2015 that provide data and information on toxicological evidence of respiratory and immunological effects resulting from PM exposure. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential epidemiology studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

#### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

#### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

#### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

## **TASK 10 – PARTICLE TRANSLOCATION FROM RESPIRATORY SURFACES AND MODIFYING FACTORS**

### ***Task 10a. PREPARE WRITTEN SECTION ON PARTICLE TRANSLOCATION FROM RESPIRATORY SURFACES AND MODIFYING FACTORS***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing the translocation of inhaled particles from their site of deposition and factors affecting their rate or magnitude of translocation and movement through cell membranes. As part of the 2009 PM ISA, Section 4.3.3 described evidence of particle transport across cell membranes and movement from their site of deposition by mechanisms other than mucociliary and macrophage mediated clearance. Subsequently, Section 4.3.4 described factors such as reductions in epithelial integrity which may acutely increase particle translocation from luminal respiratory surfaces. The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D. or equivalent and research experience in engineering, toxicology or other biological sciences relevant to inhaled particle dosimetry. The ideal author(s) would have at least 10 publications related to the investigation of particle disposition in the respiratory tract and/or in vitro studies of particle translocation. Potential authors shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 10a*, the Contractor shall perform the following subtasks.

#### **Subtasks**

##### **(1) Literature Search**

The Contractor shall perform a detailed literature search in HERO of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that are germane to their topic. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential experimental studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

##### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

##### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

##### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**



## **TASK 11 – CONTROLLED HUMAN EXPOSURE STUDIES EVIDENCE OF RESPIRATORY AND IMMUNOLOGICAL EFFECTS OF PM EXPOSURE**

### ***Task 11a. PREPARE WRITTEN SECTIONS ON CONTROLLED HUMAN EXPOSURE STUDIES EVIDENCE OF RESPIRATORY AND IMMUNOLOGICAL EFFECTS OF PM EXPOSURE***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing evidence from controlled human exposure (CHE) studies of respiratory and immunological effects resulting from exposure to PM. As part of the 2009 PM ISA, Section 6.3 described evidence of respiratory and immunological effects resulting from PM exposure. For respiratory effects, this included altered pulmonary function, airway hyperresponsiveness, pulmonary injury, altered epithelial barrier function, and pulmonary oxidative stress. For immunological effects, this included innate and adaptive immune responses such as inflammation, allergic sensitization and host defense. These areas should be included in the search of the literature for newer publications on PM. The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D., M.D., or equivalent and research experience in immunology, physiology, toxicology, or other biological sciences relevant to respiratory or immunological effects in CHE studies of PM exposure. The ideal author(s) would have at least 10 publications related to the investigation of respiratory or immunological effects resulting from PM exposure in CHE studies. Potential authors shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 11a*, the Contractor shall perform the following subtasks.

#### **Subtasks**

##### **(1) Literature Search**

The Contractor shall perform a detailed literature search in HERO of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that are germane to their topic. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential experimental studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

##### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

##### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

- (4) The Contractor shall provide written sections to EPA by March 31, 2016.

## **TASK 12 – TOXICOLOGICAL EVIDENCE OF CARDIOVASCULAR AND CARDIOMETABOLIC EFFECTS OF PM EXPOSURE**

### ***Task 12a. PREPARE WRITTEN SECTIONS ON TOXICOLOGICAL EVIDENCE OF CARDIOVASCULAR AND CARDIOMETABOLIC EFFECTS OF PM EXPOSURE***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing the toxicological evidence of cardiovascular and cardiometabolic effects resulting from exposure to PM. As part of the 2009 PM ISA, Sections 6.2 and 7.2 described toxicological evidence of cardiovascular effects of PM exposure including but not limited to heart rate, heart rate variability, ischemia/reperfusion, vasomotor function, blood pressure, cardiac contractility, systemic inflammation, hemostasis, thrombosis, coagulation and oxidative stress. These effects, along with cardiometabolic effects, should be included in the search of the literature for newer publications on PM. The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D., M.D., or equivalent and research experience in physiology, toxicology or other biological sciences relevant to cardiovascular toxicological effects of PM exposure. The ideal author(s) would have at least 10 publications related to the investigation of cardiovascular toxicology of PM exposure. Potential authors shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 11a*, the Contractor shall perform the following subtasks.

#### **Subtasks**

##### **(1) Literature Search**

The Contractor shall perform a detailed literature search in HERO of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that are germane to their topic. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential experimental studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

##### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.



### (3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

### (4) The Contractor shall provide written sections to EPA by March 31, 2016.

## **TASK 13 – CONTROLLED HUMAN EXPOSURE STUDIES EVIDENCE OF CARDIOVASCULAR AND CARDIOMETABOLIC EFFECTS OF PM EXPOSURE**

### ***Task 13a. PREPARE WRITTEN SECTIONS ON CONTROLLED HUMAN EXPOSURE STUDIES EVIDENCE OF CARDIOVASCULAR AND CARDIOMETABOLIC EFFECTS OF PM EXPOSURE***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing evidence from controlled human exposure studies of cardiovascular and cardiometabolic effects from exposure to PM. As part of the 2009 PM ISA, Section 6.2 described evidence of cardiovascular effects of PM exposure including but not limited to heart rate, heart rate variability, ischemia, vasomotor function, blood pressure, systemic inflammation and oxidative stress, hemostasis, and thrombosis. These effects, as well as cardiometabolic effects, that should be included in the search of the literature for newer publications on PM. The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D., M.D., or equivalent and research experience in physiology, toxicology or other biological sciences relevant to cardiovascular toxicological effects of PM exposure. The ideal author(s) would have at least 10 publications related to the investigation of cardiovascular toxicology of PM exposure. Potential authors shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 12a*, the Contractor shall perform the following subtasks.

#### **Subtasks**

##### (1) Literature Search

The Contractor(s) shall perform a detailed literature search in HERO of all new peer-reviewed, published (or accepted for publication November 1, 2015) articles and reports that are germane to their topic. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential experimental studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

##### (2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

**TASK 14 – TOXICOLOGICAL EVIDENCE OF CANCER, GENOTOXICITY, EPIGENETICS, AND MUTAGENICITY OF PM EXPOSURE**

***TASK 14a. PREPARE WRITTEN SECTIONS ON TOXICOLOGICAL EVIDENCE OF CANCER, GENOTOXICITY, EPIGENETICS, AND MUTAGENICITY***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing the toxicological evidence of carcinogenic, epigenetic, genotoxic, and mutagenic effects from exposure to PM. As part of the 2009 PM ISA, Section 7.5 described toxicological evidence of carcinogenic, epigenetic, genotoxic and mutagenic effects of PM exposure, broad outcome areas that should be included in the search of the literature for newer publications on PM. The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D., M.D., or equivalent and research experience in physiology, toxicology or other biological sciences relevant to carcinogenic, genotoxic, mutagenic and epigenetic toxicological effects of PM exposure. The ideal author(s) would have at least 10 publications related to the investigation of carcinogenic, genotoxic, mutagenic and epigenetic toxicology of PM exposure. Potential authors shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 12a*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature search in HERO of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that are germane to their topic. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential experimental studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

**TASK 15 – TOXICOLOGICAL EVIDENCE OF REPRODUCTIVE AND DEVELOPMENTAL EFFECTS OF PM EXPOSURE**

***Task 15a. PREPARE WRITTEN SECTIONS ON TOXICOLOGICAL EVIDENCE OF REPRODUCTIVE AND DEVELOPMENTAL EFFECTS OF PM EXPOSURE***

The purpose of this task is to update and revise the written review (delivered under WA 1-60) describing the toxicological evidence of reproductive and developmental effects from exposure to PM. As part of the 2009 PM ISA, Section 7.4 described toxicological evidence of reproductive and developmental effects from PM exposure including but not limited to male reproductive effects, female reproductive effects, and developmental effects; these broad outcome categories may be incorporated in sections prepared by author(s). The contractor shall also participate in telephone meetings as necessary (e.g., monthly) with EPA staff and other ISA authors.

The author(s) shall have a Ph.D., M.D., or equivalent and research experience in physiology, toxicology or other biological sciences relevant to reproductive and developmental toxicology effects of PM exposure as described above. The ideal author(s) would have at least 10 publications related to the investigation of reproductive and developmental toxicology of PM exposure. Potential authors shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 12a*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature search in HERO of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that are germane to their topic. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search that have been identified as potential experimental studies, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote;

and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

**Task 16. PREPARE A WRITTEN SECTION ON THE VISIBILITY EFFECTS OF PM**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant evidence on the visibility effects of PM. Preference studies related to visibility shall be based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. Studies of light scattering as pertaining to visibility shall also be based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on visibility shall have a Ph.D. and research experience related to PM visibility. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the visibility effects of PM. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 16*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on visibility preference and light scattering studies that were not included in the previous PM ISA. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

**Task 17. PREPARE A WRITTEN SECTION ON PM MODELING AND DATA FUSION FOR EXPOSURE ASSESSMENT**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant evidence on PM Modeling and Data Fusion for Exposure Assessment. Studies on PM modeling used in exposure assessment, including but not limited to chemical transport modeling (e.g., CMAQ, GEOS-Chem), and dispersion modeling shall be based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. Additionally, studies of data fusion techniques (e.g., assimilation of satellite data with surface measurements and land use variables) used in exposure assessment shall be based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on PM modeling and data fusion for exposure assessment shall have a Ph.D. and research experience related to chemical transport modeling and data fusion in atmospheric science. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on chemical transport modeling and data fusion for PM exposure assessment. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 17*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on PM modeling and data fusion for exposure assessment studies. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task

4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

**Task 18. PREPARE WRITTEN SECTIONS ON SOURCES, CHEMISTRY, NUCLEATION, MEASUREMENT, CONCENTRATIONS, AND SPATIAL VARIABILITY OF ULTRAFINE PARTICLES**

There are six sub-sections of the section on ultrafine particles, which are described in Tasks 6a (sources of ultrafine particles), 6b (chemistry of ultrafine particles), 6c (nucleation of ultrafine particles), 6d (measurement of ultrafine particles), 6e (concentrations of ultrafine particles), and 6f (spatial variability of ultrafine particles). Provided the criteria for evaluating an author(s)' expertise that are described below are met, one expert may write more than one subsection.

**Task 18a. Sources of Ultrafine Particles**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on sources of ultrafine particles based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on sources of ultrafine particles shall have a Ph.D. and research experience relevant to sources of ultrafine particles. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the sources of ultrafine particles. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 18a*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on sources of ultrafine particles. The Contractor shall conduct

searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

***Task 18b. Chemistry of Ultrafine Particles***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on chemistry of ultrafine particles based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on chemistry of ultrafine particles shall have a Ph.D. and research experience relevant to chemistry of ultrafine particles. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the chemistry of ultrafine particles. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 18b*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on chemistry of ultrafine particles. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1)



potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

***Task 18c. Nucleation of Ultrafine Particles***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on nucleation of ultrafine particles based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on nucleation of ultrafine particles shall have a Ph.D. and research experience relevant to nucleation of ultrafine particles. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the nucleation of ultrafine particles. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 18c*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on nucleation of ultrafine particles. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section



The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

***Task 18d. Measurement of Ultrafine Particles***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on measurement of ultrafine particles based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on measurement of ultrafine particles shall have a Ph.D. and research experience relevant to measurement of ultrafine particles. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the measurement of ultrafine particles. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 18d*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on measurement of ultrafine particles. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

### ***Task 18e. Concentrations of Ultrafine Particles***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on concentrations of ultrafine particles based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on concentrations of ultrafine particles shall have a Ph.D. and research experience relevant to concentrations of ultrafine particles. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the concentrations of ultrafine particles. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 18e*, the Contractor shall perform the following subtasks.

#### **Subtasks**

##### **(1) Literature Search**

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on concentrations of ultrafine particles. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

##### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

##### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

- (4) The Contractor shall provide written sections to EPA by March 31, 2016.

***Task 18f. Spatial Variability of Ultrafine Particles***

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant epidemiologic evidence on spatial variability (i.e., microscale, middle scale, neighborhood scale, and urban scale) of ultrafine particles based on literature available since completion of the 2009 PM ISA, while considering the new literature in the context of the older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on spatial variability of ultrafine particles shall have a Ph.D. and research experience relevant to spatial variability of ultrafine particles. The author(s) shall have no fewer than 4 publications and at least 3 years of experience researching and publishing on the spatial variability of ultrafine particles. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 18f*, the Contractor shall perform the following subtasks.

**Subtasks**

(1) Literature Search

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication through November 1, 2015) articles and reports that have been imported into HERO that provide data and information on spatial variability (i.e., microscale, middle scale, neighborhood scale, and urban scale) of ultrafine particles. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. The Contractor shall request that these additional relevant papers be added to HERO. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

(2) Update and Revise Draft Section

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

(3) Update and Revise Tables Containing Study Specific Details

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

(4) The Contractor shall provide written sections to EPA by March 31, 2016.

### **Task 19. PREPARE A WRITTEN SECTION ON THE RADIATIVE FORCING AND CLIMATE EFFECTS OF PM**

The Contractor shall update and revise the written review (delivered under WA 1-60) of the most relevant evidence on the radiative forcing and climate effects of PM. Studies, related to chemistry-climate interactions in the troposphere and how short-lived particles affect climate, shall focus on literature available since completion of the 2009 PM ISA while considering the new literature in the context of older studies. The contractor shall participate in 4-6 telephone meetings as needed with EPA staff and other PM ISA authors.

The author(s) of the section of the PM ISA on radiative forcing and climate effects of PM shall have a Ph.D. (or equivalent degree) and research experience related to the role of PM in radiative forcing and climate change. The author(s) shall have no fewer than 30 publications with at least 10 years of experience that includes research and publication on climate change and topics relevant to the climate effects of PM, such as radiative forcing. Potential author(s) shall be asked to submit a bio-sketch for assessing their qualifications; the bio-sketches will be reviewed by the EPA WAM who will provide comment on the capabilities of the proposed author(s).

To successfully complete *Task 19*, the Contractor shall perform the following subtasks.

#### **Subtasks**

##### **(1) Literature Search**

The Contractor shall perform a detailed literature survey of all new peer-reviewed, published (or accepted for publication November 1, 2015) articles and reports (e.g., Intergovernmental Panel on Climate Change Fifth Assessment Report, Royal Society and U.S. National Academy of Sciences Climate Change: Evidence and Causes) that have been imported into HERO that provide data and information on radiative forcing and climate change studies relating to PM. The Contractor shall conduct searches within HERO of all studies identified in EPA's broad PM literature search, and document selection of keywords used in this search. For this purpose, the climate-relevant keywords already developed under contract EP-C-09-009, WA 4-94 (Attachment 7) shall be used to search within the broad PM literature search. The Contractor shall also keep track of whether all relevant studies have been identified during EPA's broad search. For literature not located in HERO, the contracted author(s) are responsible for maintaining a log of the databases searched and search strategies for identifying relevant papers. As detailed in Task 4, the Contractor shall keep track of two sets of references: (1) potentially considered literature, i.e. those studies identified by authors during their key word searches in Endnote; and, (2) considered literature, i.e. any reference where more than the title was read.

##### **(2) Update and Revise Draft Section**

The Contractor shall revise section per comments provided by EPA and add additional studies published through November 1, 2015.

##### **(3) Update and Revise Tables Containing Study Specific Details**

The Contractor shall update tables containing extracted study data and revise tables as needed based upon feedback from EPA.

##### **(4) The Contractor shall provide written sections to EPA by March 31, 2016.**

#### IV. **SCHEDULE OF DELIVERABLES**

Deliverables/Meetings	Anticipated Completion Dates
Task 1- Conference Call	Within 3 days of award
Task 2- Prepare QAPP	Within 5 days of award
Task 3a - Identify and Recruit Expert Authors	Within 5 days of award
Task 4a - Obtain HERO access for authors and other relevant personnel	Within 5 days of award
Task 4b - Generate section specific reference lists	March 31, 2016
Task 4c - Provide final list of considered references	March 31, 2016
Task 4d - Provide tables with study data	March 31, 2016
Tasks 5-19, Provide drafts of sections that are appropriate for peer input	March 31, 2016
Task 4c, Provide final list of considered references (with additional search terms if applicable)	March 31, 2016

## **V. Management Controls**

1. The contractor shall certify there is no conflict of interest. The contractor shall provide the following conflict of interest certification in the workplan:

I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this work assignment exist. Personnel, who perform work under this work assignment, or relating to the work assignment, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this work assignment have been reported to the Project Officer or are attached, if applicable.

2. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

3. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

4. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

## **VI. Notice Regarding Guidance Provided Under this Project**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

## **VII. Special Conditions and Assumptions**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at <http://www.epa.gov/oppt/greenmeetings/>.

### **VIII. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

#### **X. Work Assignment Manager (WAM)**

Ellen Kirrane, Ph.D.  
B231-L, RTP 27711  
(919) 541- 1340  
FAX (919) 541- 2985  
[kirrane.ellen@epa.gov](mailto:kirrane.ellen@epa.gov)

James Brown, Ph.D (Alternate)  
B220K, RTP 27711  
919-541-0765  
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[Brown.james@Epa.gov](mailto:Brown.james@Epa.gov)

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

2-60

☐ Other☐ Amendment Number:

Contract Number

EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Base

Option Period Number 2

Title of Work Assignment/SF Site Name

Authorship of Specific Section

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

A. Assessment Issues and Documents

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 11/01/2015 To 10/31/2016

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:

11/01/2013 To 10/31/2016

Cost/Fee: \$0.00

LOE: 0

This Action:

\$235,451.00

2,033

Total:

\$235,451.00

2,033

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

12/03/2015

Cost/Fee: \$235,451.00

LOE: 2,033

Cumulative Approved:

Cost/Fee: \$235,451.00

LOE: 2,033

Work Assignment Manager Name Ellen Kirrane

Branch/Mail Code:

(Signature)

(Date)

Phone Number 919-541-1340

FAX Number:

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

(Signature)

(Date)

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

Branch/Mail Code:

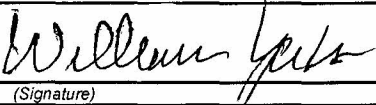
(Signature)

(Date)

Phone Number:

FAX Number:

Contracting Official Name



12/24/15

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2852

FAX Number: 513-487-2107